REMARKS

Upon entry of this amendment, claims 1-6, 14, 46-51 and 54-55 are pending in the instant application. Applicants have herein cancelled claims 9, 10, 12, 19-45, 52 and 53, without prejudice. Applicants reserve the right to pursue the subject matter of these claims in a later application. In this response, claims 1, 4-6, 14 and 46 have been amended and claims 54-55 have been added. The claims, as amended and added herein, are fully supported by the instant specification. Accordingly, no new matter has been added.

INFORMATION DISCLOSURE STATEMENT

Applicants acknowledge the Examiner's statement that the Information Disclosure Statement filed July 31, 2002 failed to comply with 37 CFR § 1.97, § 1.98 and MPEP § 609 and that the information referred to therein has not been considered as to the merits.

PRIORITY

The Examiner has objected to the priority claim as being improperly phrased. Applicants have amended the priority claim, such that priority application U.S.S.N. 09/443,199 is not incorporated by reference in its entirety. Applicants believe that this amendment overcomes the objection and request that this objection be withdrawn.

DRAWINGS

Applicants acknowledge the Draftsperson's objection to the drawings filed in the instant specification. Applicants have provided corrected drawings in compliance with 37 CFR § 1.84. Therefore, Applicants respectfully request withdrawal of the present objection.

CLAIM REJECTIONS UNDER 35 USC § 112, FIRST PARAGRAPH

Claims 4-6, 9 and 45 have been rejected under 35 U.S.C. § 112, first paragraph for allegedly containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention (New Matter Rejection).

Applicants have cancelled claims 9 and 45 and amended claims 4-6. Specifically, claims 4-6 have been amended herein to delete the phrase "at least 10 contiguous bases." Claims 4-6 now recite a nucleic acid molecule of between 10 to 50, 10 to 40 and 10 to 30 bases in length, respectively. Applicants submit, and the Examiner states (*See*, Office Action at page 6), that the originally filed specification teaches these lengths on pages 4 and 6.

Therefore, Applicants assert that claims 4-6 as amended herein do not recite new matter and meet the provisions of 35 U.S.C. § 112, first paragraph. Applicants request that this rejection be withdrawn.

Claims 1-6, 9-10, 12, 14 and 45-53 have also been rejected under 35 U.S.C. § 112, first paragraph for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention (Written Description Rejection).

The rejection is moot with respect to claims 9, 10, 12, 45, 52 and 53, which have been cancelled. The rejection will be addressed as it relates to amended claims 1, 4-6, 14 and 46 and to new claims 54-55.

The Examiner asserts that although a sequence consisting of SEQ ID NO: 509 meets the written description provisions of 35 U.S.C. § 112, first paragraph, claims directed to encompass gene sequences, hybridization sequences, fragments, sequences from other sequences, variants and homologous sequences comprising SEQ ID NO: 509 fail to meet the written description provisions.

Applicants amended claims 1, 4-6, 14, 46 and added new claims 54-55 to claim sequences directed specifically to SEQ ID NO: 509 or sequences consisting of SEQ ID NO: 509. Therefore, as amended herein, pending claims 1-6, 14, 46-51 and 54-55 are directed to isolated nucleic acid molecules consisting of the polymorphic nucleotide sequence of SEQ ID NO: 509 and oligonucleotide sequences which hybridize to the polymorphic nucleotide sequence of SEQ ID NO: 509, and complementary sequences consisting of SEQ ID NO: 509.

Applicants submit that as amended herein, pending claims 1-6, 14, 46-51 and 54-55 meet the written description provisions of 35 U.S.C. § 112, first paragraph. Applicants respectfully request that this rejection be withdrawn.

CLAIM REJECTIONS UNDER 35 USC § 101

Claims 1-6, 9-10, 12, 14 and 45-53 have been rejected under 35 U.S.C. § 101 for allegedly not being supported by either a specific, substantial, and credible utility or, in the alternative, a well-established utility. Applicants traverse.

The rejection is moot with respect to claims 9, 10, 12, 45, 52 and 53, which have been cancelled. The rejection will be addressed as it relates to amended claims 1, 4-6, 14 and 46 and to new claims 54-55.

It is the Examiner's position that the asserted specific utilities for the claimed invention are not considered to be substantial or credible utilities because the utilities are generally applicable to broad classes of this subject matter and the specification only discloses that SEQ ID NO: 509 is related to a KGF precursor (Office Action at pages 9-11). The Examiner further states that a polynucleotide comprising the polymorphic nucleic acid of SEQ ID NO: 509 would not be useful for forensic identification, paternity testing and in tracking the past migration of modern humans as these applications are generic to any nucleic acid comprising a polymorphic site (Office Action at page 12).

As amended herein, pending claims 1-6, 14, 46-51 and 54-55 are directed to isolated nucleic acid molecules consisting of the polymorphic nucleotide sequence of SEQ ID NO: 509 or a complement thereof. While Applicants agree with the Examiner's assertion that the use of SNPs is generic for forensic identification, paternity testing and past migration tracking, Applicants assert that *specific* SNPs, with *specific* nucleotide sequences which have a *specific* application with respect to forensic identification, paternity testing and past migration tracking are *not,* as the, Examiner contends, generic. The identification of *specific* polymorphic sequences such as the polynucleotides of the invention, are critical to the advancement of the fields of forensic medicine, population genetics and paternity testing. Without such *specific* identification the application of SNPs to these generic fields would be moot. Accordingly Applicants submit that the claimed polynucleotide consisting of the polymorphic nucleotide

sequence of SEQ ID NO: 509 has a *specific* and *substantial* utility in the fields of forensic medicine, population genetics and paternity testing, which is not dependent upon the function or homology of SEQ ID NO: 509 to a known gene.

SNPs are critical to the field of forensic medicine. The polynucleotide consisting of the polymorphic nucleotide sequence of SEQ ID NO: 509 can be amplified and utilized in forensic genotyping, the results of which can be accurate and quantifiable (*See* pg 41, line 16 – pg 43, line 16). These genotyping assays are performed using polynucleotide of the present invention, as well as, techniques commonly used in the art. Thus, the polynucleotide consisting of the polymorphic nucleotide sequence of SEQ ID NO: 509 of the present invention are used to identify individuals who are differentiated by the disclosed polymorphism. This has further utility in assessing the successfulness of organ transplantation and *in vitro* fertilization.

The specific polynucleotide consisting of the polymorphic nucleotide sequence of SEQ ID NO: 509 also has a credible and specific utility in paternity testing to separate and identify individuals who have the claimed polymorphism (*See* pg 43, line 17 – pg 44, line 20).

Data generated by the polynucleotide consisting of the polymorphic nucleotide sequence of SEQ ID NO: 509, has utility beyond forensic or paternity identification. It has a credible utility in the field of population genetics. It can also be used to reconstruct the past migration history of modern humans who possess the polymorphism. Populations of the same species in different geographical regions tend to differ genetically. Such differences may in part reflect their adaptation to different environments, or they may simply be the result of change events in the evolutionary histories of the populations since the divergence. SNPs analysis tools, including the claimed polynucleotide consisting of the polymorphic nucleotide sequence of SEQ ID NO: 509, can be used to describe the nature of genetic differentiation that is observed in real populations, and understand the mechanisms for it.

Accordingly, Applicants submit that one skilled in the art would recognize the specific, real world utility of the polynucleotide of the present invention, which consists of the polymorphic nucleotide sequence of SEQ ID NO: 509 and oligonucleotide sequences which hybridize to the polymorphic nucleotide sequence of SEQ ID NO: 509, and its complementary sequences, in the fields of forensics, paternity testing and population genetics (*See* pg 41, line 16 – pg 43, line 16; pg 43, line 17 – pg 44, line 20; pg 48, line 25 – pg 50, line 11). Thus the

polynucleotide, which consists of the polymorphic nucleotide sequence of SEQ ID NO: 509 and oligonucleotide sequences which hybridize to the polymorphic nucleotide sequence of SEQ ID NO: 509, and its complementary sequences, has an art-recognized specific, substantial, and credible utility.

Therefore, Applicants respectfully request that this rejection be withdrawn.

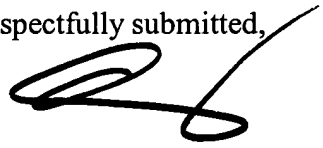
Claims 1-6, 9-10, 12, 14 and 45-53 are also rejected under 35 U.S.C. § 112, first paragraph for alleging that since the invention is not supported by either a specific or substantial asserted utility, one skilled in the art would not know how to use the claimed invention.

Applicants traverse. For the reasons set forth above, Applicants submit that the claimed invention has a specific and substantial or well-established utility. Therefore, this rejection is now moot as it applies to pending claims 1-6, 14, 46-51 and 54-55 and should be withdrawn.

CONCLUSION

On the basis of the foregoing amendments, Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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Version with Markings to Show Changes

In the Specification:

The priority information on page 1 was amended as follows:

-- This application is a continuation-in-part of U.S.S.N. 09/442,849, filed November 17, 1999, which claims priority to U.S.S.N. 09/442,129 [and U.S.S.N. 09/443,199], [both] filed November 16, 1999, and to U.S.S.N. 60/109,024, filed November 17, 1998. The contents of these applications are incorporated herein by reference in their entirety. U.S.S.N. 09/442,849, filed November 17, 1999, also claims priority to U.S.S.N. 09/443,199, filed November 16, 1999. --

In the Claims:

1. (Twice Amended) An isolated nucleic acid molecule consisting of [polynucleotide comprising] the polymorphic nucleotide sequence of SEQ ID NO: 509.

2. (Amended) The nucleic acid molecule [polynucleotide] of claim 1, wherein said nucleic acid molecule [polynucleotide sequence] is DNA.

3. (Amended) The nucleic acid molecule [polynucleotide]of claim 1, wherein said nucleic acid molecule [polynucleotide sequence] is RNA.

4. (Twice Amended) An isolated nucleic acid molecule [The polynucleotide of claim 1, wherein said polynucleotide sequence is] wherein said nucleic acid molecule comprises: a) between [about] 10 and [about] 50 nucleotides [in length, and wherein at least 10 contiguous bases] of SEQ ID NO: 509 and b) [include] the nucleotide corresponding to position 26 of SEQ ID NO: 509, wherein said nucleotide is not an adenine.

5. (Twice Amended) The nucleic acid molecule [polynucleotide] of claim 4 [1], wherein said nucleic acid molecule [polynucleotide sequence] is between [about] 10 and [about] 40 nucleotides [nucleotides in length, and wherein at least 10 contiguous bases include the nucleotide corresponding to position 26 of SEQ ID NO: 509].

6. (Amended) The nucleic acid molecule [polynucleotide] of claim 4 [1], wherein said nucleic acid molecule [polynucleotide sequence] is between [about] 10 and [about] 30 nucleotides [nucleotides in length, and wherein at least 10 contiguous bases include the nucleotide corresponding to position 26 of SEQ ID N0: 509].

9-10. Cancelled.

12. Cancelled.

14. (Twice Amended) An isolated allele-specific oligonucleotide that hybridizes to [a first polynucleotide at a polymorphic site encompassed therein, wherein the first polynucleotide comprises] the polymorphic nucleotide sequence of SEQ ID NO: 509.

19-45. Cancelled.

46. (Amended) An isolated nucleic acid molecule consisting of [polynucleotide comprising] a sequence complementary to the polymorphic nucleotide sequence of SEQ ID NO: 509.

47. (Amended) The nucleic acid molecule [polynucleotide] of claim 46, wherein said nucleic acid molecule [polynucleotide sequence] is DNA.

48. (Amended) The nucleic acid molecule [polynucleotide]of claim 46, wherein said nucleic acid molecule [polynucleotide sequence]is RNA.

49. (Amended) The nucleic acid molecule [polynucleotide] of claim 46, wherein said nucleic acid molecule [polynucleotide sequence] is between [about] 10 and [about] 50 nucleotides [bases in length].

50. (Amended) The nucleic acid molecule [polynucleotide] of claim 46, wherein said nucleic acid molecule [polynucleotide] is between [about] 10 and [about] 40 nucleotides [bases in length].

51. (Amended) The nucleic acid molecule [polynucleotide] of claim 46, wherein said nucleic acid molecule [polynucleotide] is between [about] 10 and [about] 30 nucleotides [bases in length].

52-53. Cancelled.

-- 54. (New) The isolated nucleic acid molecule of claim 4, wherein the nucleotide at position 26 is a guanosine.

55. (New) An isolated nucleic acid molecule consisting of a sequence complementary to the isolated nucleic acid molecule of claim 4. --